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**UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460**

OFFICE OF PESTICIDES AND TOXIC SUBSTANCES

MEMORANDUM

DATE: November 14, 2008

SUBJECT: Alternate Manufacturing Process and Alternate CSF for Bedoukian Trans-11-Tetradecenyl Acetate Technical Pheromone

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| Decision Number: | 401030 |
| DP Number: | 357133 |
| Submission Number: | 834670 |
| EPA Reg. Number: | 52991-8 |
| Chemical Class: | Biochemical |
| PC Code: | 129019 |
| CAS Number: | 33189-72-9 |
| Active Ingredient Tolerance Exemption: | N/A |
| MRID Number: | 475175-01 |

FROM: Nina Simeonova, Chemist, NOWCC-SEE Enrollee
Biopesticides & Pollution Prevention Division (7511P)

N. Simeonova

TO: Andrew Bryceland, Regulatory Action Leader
Biochemical Pesticides Branch
Biopesticides & Pollution Prevention Division (7511P)

THE FOLLOWING CONTAINS CONFIDENTIAL BUSINESS INFORMATION

ACTION REQUESTED

On behalf of Bedoukian Research, Inc., Keller and Heckman LLP request registration of alternate CSF for Bedoukian Trans-11-Tetradecenyl Acetate Technical Pheromone, EPA

Reg. No. 52991-8.

Trans-11-Tetradecen-1-yl Acetate is used in the program for eradication of Light Brown Apple Moth in California. Large amounts of this technical product are recently in demand. In order to meet the growing needs for Trans-11-Tetradecen-1-yl Acetate an alternate manufacturing process has been developed at Bedoukian Research Inc., which provides better flexibility about the availability and the prices of the starting materials and intermediates, while keeping the quality of the MU product high. The starting materials for the alternate manufacturing process are available in larger quantities than the currently registered. By using the alternate manufacturing process it is easier to meet the growing needs for Z-11-Tetradecen-1-yl Acetate.

The currently registered manufacturing process (MRID 450140-01) contains [REDACTED]

In support of the request for registration of the alternate manufacturing process the applicant submitted the study MRID 475175-01 "Bedoukian Trans-11-Tetradecenyl Acetate Technical Pheromone, EPA Reg. No. 52991-8. Alternate Confidential Statement of Formula".

CONCLUSIONS AND RECOMMENDATIONS

1. The alternate manufacturing process, described in MRID 475175-01, employs different reaction scheme and different starting materials in comparison to the currently registered basic process. The E: Z ratio is [REDACTED] in self-proposed certified limits. This ratio is included in the currently registered broad range. The manufacturing impurities in the alternate product are studied much more in depth than those in the currently registered product. They are also different, but generally are from the same class of the straight chain substituted hydrocarbons, in small amounts and not of specific toxicological concern.
2. Based on the conclusions in Point 1 the application for registration of an alternate manufacturing process for Bedoukian Trans-11-Tetradecenyl Acetate Technical Pheromone (EPA Reg. No. 52991-8) is found to be in compliance with the requirements set forth in 40CFR§152.43(b)1-4. The currently registered basic manufacturing process (CSF dated 01/14/2005, MRID) allows variations of the ratio E/Z in broad ranges, the total of the both isomers remains the same (98%) and the manufacturing impurities are similar. The self-proposed certified limits based on the preliminary analysis and on production experience are acceptable.
3. The application for alternate CSF of Bedoukian Trans-11-Tetradecenyl Acetate Technical Pheromone (EPA Reg. No. 52991-8) produced by an alternate manufacturing process is acceptable, provided the following deficiencies are resolved:

- Draft Alternate CSF (Form 8570-4) must be prepared on the base of the data in Table 3, p.18/119 and submitted to the Agency;
- The mistake about the Upper Certified Limit of [REDACTED] in Table 3 must be corrected.

STUDY SUMMARY

MRID 475176-01. Bedoukian Trans-11-Tetradecenyl Acetate Technical Pheromone. Vol. 1A. Alternate Confidential Statement of Formula.

The study contains CBI. It is not conducted in compliance with the requirements of 40CFR§160. It contains the rationale for developing an alternate production process for Bedoukian Trans-11-Tetradecenyl Acetate Technical Pheromone.

In Confidential Attachment the study contains the description of the starting materials and the intermediates by Chemical Name, CAS #, Chemical Formula and % purity. The alternate production process is described step by step by the chemical equation, the amounts of the materials, the conditions and the equipment used.

Several manufacturing impurities are identified by GC/MS. The explanation about their formation is satisfactory. The analytical method is described in compliance with the corresponding data requirements. The results from the preliminary analysis are presented in Table 1(p. 11/119). They are treated statistically to obtain the average values of the major ingredients, the impurities and the standard deviations. The results are presented in Table 2 (p. 17/116). The proposed by the applicant certified limits are presented in Table 3 (p.18/119). The Certification Statement according to 40CFR§158.350 (e) is submitted.

Appendix 1 contains the chromatograms and the mass spectra used to identify the major ingredient of the pheromone.

Appendix 2 contains the gas-chromatograms from the preliminary analysis.

Appendix 3 contains the MSDSs of the starting materials and the intermediates used in the alternate manufacturing process.

cc: N. Simeonova, A. Bryceland, IHAD Database, BPPD Chron File, IHAD/ARS.
N. Simeonova, FT, PY-S. 11/14/2008.